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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,077	04/28/2005	Kyung-Lim Lee	P27808	2398

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EXAMINER	
GRAFFEO, MICHEL	
ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 04/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/533,077	LEE ET AL.	
	Examiner	Art Unit	
	Michel Graffeo	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Action

Claims 17-36 are pending and examined.

Applicant has amended claims 21, 27, 31, 33 and 35 and provided arguments for the patentability of claims 17-36 in the response filed 27 March 2006.

Applicant's arguments, see response, filed 27 March 2006, have been fully considered and are persuasive. Therefore, the rejections of claims 17-36 under 35 USC §112 and 35 USC §103, have been withdrawn. However, upon further consideration, a new ground(s) of rejection is made. Any rejection not specifically stated in this Office Action has been withdrawn.

Claim Rejections - 35 USC § 112 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17-21 and 26-27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating certain allergies to the extent that a mouse model demonstrates reduced symptoms of allergic rhinitis and lower IgE levels as described in Hamaguchi et al. below, does not reasonably

provide enablement for the treatment of any and all allergic diseases caused by HRF with any and all benzimidazole compounds nor for the treatment without any specified endpoint. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

In this regard, the application disclosure and claims have been compared per the factors indicated in the decision *In re Wands*, 8 USPQ2nd 1400 (Fed. Cir. 1988) as to undue experimentation.

The factors include:

1) the nature of the invention;
2) the breadth of the claims;
3) the predictability or unpredictability of the art;
4) the amount of direction or guidance presented;
5) the presence or absence of working examples;
6) the quantity of experimentation necessary;
7) the state of the prior art; and ,
8) the relative skill of those skilled in the art.

Each factor is addressed below on the basis of comparison of the disclosure, the claims and the state of the art in the assessment of undue experimentation.

1) the nature of the invention; the invention is directed to a method of treating any and all allergic diseases caused by HRF with any and all benzimidazole compounds but has not recited the step(s) that (a) result in preventing nor (b) have a specified end result of the treatment.

2) the breadth of the claims; the scope of the method claims includes any and all allergic diseases caused by HRF with any and all benzimidazole compounds including those that have not yet been discovered.

3) the predictability or unpredictability of the art; the ability of treating of any and all allergic diseases caused by HRF with any and all benzimidazole compounds is not yet known in the art. See for example, US Patent No. 6,861,425 to Ito et al. which teaches benzimidazole compounds that are useful as analgesics.

No experimental evidence supporting the contention that the claim specified actives would actually treat all of these diseases by simply administering the claim generalized active agents has not been demonstrated nor practice the invention without an envisaged endpoint or result of the treatment (note the absence of such recitation in the current claim(s)). The specification fails to enable one of ordinary skill in the art to practice the presently claimed method for practicing same without a specific endpoint for the treatment of the claimed diseases.

4) the amount of direction or guidance presented; the specification does not provide any guidance in terms of treating of any and all allergic diseases caused by HRF with any and all benzimidazole compounds.

5) the presence or absence of working examples; The applicant has not provided any competent evidence or disclosed any tests that are highly predictive for the effects of the instant composition. Note that in cases involving

physiological activity such as the instant case, "the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved". See In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

6) the quantity of experimentation necessary; the quantity of experimentation would be undue to one of skill in the art and amount to the trial and error type of experimentation without a priori expectation of success. Thus, factors such as "sufficient working examples", "the level of skill in the art" and "predictability", etc. have been demonstrated to be sufficiently lacking in the instant case for the instant method claims. To support a claim to the treatment of all allergic diseases covered in the instant claims or the like, Applicant would need to provide confirmative in vivo data supporting the treatment of a representative number of the disease as well as a method and dosage regime resulting in the treatmetn of same.

In view of the breadth of the claims, the chemical nature of the invention and unpredictability of preventing caner, and the lack of working examples regarding the activity as claimed, one skilled in the art would have to undergo an undue amount of experimentation to use the instantly claimed invention commensurate in scope with the claims.

In consideration of each of factors 1-8, it is apparent that there is undue experimentation because of variability in prediction of outcome that is not addressed by the present application disclosure, examples, teaching and guidance presented. Absent factual data to the contrary, the amount and level of experimentation needed is undue.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 17-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hamaguchi et al. TY-572, a Potent and Selective CD45 Inhibitor, Suppresses IgE-Mediated Anaphylaxis and Murine Contact Hypersensitivity Reaction, International archives of Allergy and Immunology (2001), 126 (4), 318-324 in view of US Patent No. 6,491,943 to Tsuji et al.

Hamaguchi et al. teach the use of a benzimidazole compound for the treatment of allergies such as anaphylaxis and urticaria comprising TU-572, which is considered a derivate of the claimed compounds (in current claims 17-36; see Discussion page 322) and can be found on page 320 via a reduction in IgE.

Hamaguchi et al. do not teach the use of catechins.

Tsuji et al. teach that catechins suppress histamine release (in current claims 20 and 26; see col 2 lines 14-16) and can treat allergies also via a reduction in IgE.

One of ordinary skill in the art would have been motivated to combine the above references and as combined teach the claimed invention as claimed. One of ordinary skill in the art would have been motivated to combine Hamaguchi et al. with Tsuji et al. because both are directed to the treatment of allergies via IgE. Moreover, combining agents which are known to be useful as treatments for allergies individually into a singe composition useful for the very same purpose is prima facie obvious. See In re Kerkhoven 205 USPQ 1069. Since it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose, the idea of combining TU-572 and catechin flows logically from their having been individually taught in the prior art.

Response to Arguments - 35 USC § 112 and 35 USC § 103

Applicant's arguments, see response, filed 27 march 2006, with respect to the rejection(s) of claim(s) 17-36 under 35 USC § 112 and 35 USC § 103 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon examination of the claims, a new ground(s) of rejection is made in view of Hamaguchi et al. TY-572, a Potent and Selective CD45 Inhibitor, Suppresses IgE-Mediated Anaphylaxis and Murine Contact Hypersensitivity Reaction, International

archives of Allergy and Immunology (2001), 126 (4), 318-324 in view of US Patent No. 6,491,943 to Tsuji et al.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michel Graffeo whose telephone number is 571-272-8505. The examiner can normally be reached on 9am to 5:30pm Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

14 April 2006
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